

## **REMARKS**

Reconsideration of this application and allowance of the claims is respectfully requested.

Claims 8 and 22 have been amended in accordance with the comments by the examiner. Other amendments have also been made to reduce ambiguity, not to change the scope of the claims.

The examiner has rejected claims 1-7, 9, 10, 13 and 14 as anticipated by Kawano U.S. Patent 4,867,739.

The examiner is urged to reconsider this rejection. Kawano shows a blood set having set tubing, and branch tubing 20 for connection with a source of physiological solution. However, clearly, Kawano fails to teach a second connector, which communicates with the first branch tubing in branching relation, in which the second connector “...is in removable, sealed connection with the patient connector, whereby said set comprises a closed loop of tubing.” See claim 1 of this application.

This relationship is illustrated in Fig. 3 of this present application, for example, in which patient connector 42 communicates with second connector 70 so that a loop is formed as described and claimed in the application. This may be used in priming and rinse back processes, with significant advantage.

Turning to Kawano, neither Fig. 1 nor Fig. 2 give any hint of a blood set in the closed loop configuration shown in Fig. 3 of this application. Thus, it is clear that Kawano does not anticipate claim 1 and the other cited claims, nor does it render claim 1 and the other claims obvious, because there is no purpose taught in Kawano for why such a configuration might be arranged in a blood set of the Kawano type.

In fact, it appears to be essentially impossible for the Kawano set to be placed into the configuration as described in claim 1.

Connector 2 of Fig. 2 of Kawano is carried by line 31, and is for connection with a second bag of saline solution. See Kawano, column 3, lines 29-35. Thus, introducing needle 2 is a spike, suitable for penetrating a solution container in conventional manner.

The "blood inlet 23" of Kawano Fig. 2 could be characterized as the "patient connector" as described in claim 1. If needle or spike 2 is considered to be the second connector, which communicates in branching relation with first branch tubing 20 in Kawano, it can be seen that those skilled in the art would not expect that blood inlet or patient connector 23 would be a connector of a design compatible with needle or spike 2. In the common art of blood processing sets, a patient connector is a luer-type connector, male or female. Such a connector is not compatible with a needle or spike for reliable, sealing connection.

Accordingly, those skilled in the art, having Kawano before them, would not only have no teaching of placing the set into a closed loop as described in claim 1, but it would not be possible to place a set of the design of Fig. 2 into such a closed loop, because of incompatibility between the respective connectors 2, 23.

Accordingly, it is submitted that claim 1, and its dependent claims, are patentable over Kawano.

Turning to independent claim 9 of this application, it also is rejected as anticipated by Kawano. Note in claim 9 the language "...said first branch tube communicating in branching relation with a second connector, said second connector being capable of sealing connection with said patient connector, whereby said set may

be formed into a closed loop of tubing by connection of the patient connector with the second connector after use to facilitate rinse-back of blood.”

The “connector” referred to is of course the second connector that is in branching relationship and carried on the first branch tube. To comply with claim 9, the second connector and the patient connector must be “...capable of sealing connection...”.

As previously discussed, those skilled in the art, having Kawano before them, would conclude that connector 2 and blood inlet or patient connector 23 were quite incompatible, since connector 2 is a needle or spike, and patient connector 23 is customarily a luer connector.

Accordingly, it is submitted that claim 9 and its dependent claims are also patentable over Kawano, since it is not obvious to modify the Kawano set so that it can be formed into a loop in accordance with claim 9.

Claim 15 has been rejected as unpatentable over Kawano.

Actually, it should be noted that Kawano does teach tubing that is further branched, in that branch tubing 20 has a further branch tubing 31 in Fig. 2. However, this is submitted to be a moot point, because claim 15 shares in the distinguishing limitations of claim 9, from which it depends. As discussed above, Kawano fails to teach the claim limitations as previously described.

The examiner has rejected claims 8, 11, 12, and 16-21 as unpatentable over Kawano in view of Walter U.S. Patent 2,702,034. These claims all share the limitations of one of independent claims 1 and 9, and, as such, are patentable along with those claims, as well as for their own distinctions. While variation of bore diameter size is generally a normal thing, the particular reason for the specific sizing in these claims is

significant i.e. maximizing of flow, which becomes important because of the new mode of use of the device.

Claim 22 is rejected over Kawano and Walter, further in view of Reiterman U.S. Patent 3,670,727.

While Reiterman shows a medical infusion set in which the two ends connect with each other, this is quite different from that which is called for in claim 9, from which claim 22 ultimately depends. Claim 9 requires that the second connector be in branching relation with a first branch tube, either by being connected to a branching second branch tube or being directly connected to the first branch tube. The set of Reiterman has no branching et al. It merely connects the ends together. Claim 22, however calls for the branching second connector to connect with the patient connector to form the loop.

Accordingly, claim 22 is believed to be patentable along with claim 9, from which it derives patentable distinction.

The examiner has rejected claims 23, 32, 34 and 36 on the doctrine of obviousness-type double patenting over claim 19 of U.S. Patent No. 5,772,624.

It is believed that the four rejected claims are clearly patentably distinct over claim 19 of U.S. Patent No. 5,772,624 (the "624 patent").

As the examiner notes, each of claims 23, 32, 34, and 36 call for forming a closed loop of tubing.

However, the examiner is urged to note in the '624 patent that claim 19, and its parent claim 18, fail to call for "a closed loop of tubing". In fact, a set forming a closed loop is not used! See Fig. 2, for example, of the '624 patent, in which a portion of the

set is connected with the source of cleaning/storage solution 80 in a circuit flow, but that is not a closed loop of tubing! Many blood flow sets of the prior art are used in a circuit flow arrangement, but are not in closed loop form.

Also, note that the "first conduit" called for in claim 18 of the '624 patent is reference numeral 22 in Fig. 1, while the second conduit is reference numeral 50. As taught, after use, blood handling member 28 is removed, and the ends of the first and second conduits 22, 50 are brought together, out of the configuration of Fig. 1 into the configuration of Fig. 2. The same is done with conduits 56 and 72! Then, this is connected to the source of cleaning/storage solution, and flow through the interior of the system takes place.

It is submitted that claims 18 and 19 of the '624 patent do not relate to a method of ending a process of extracorporeal blood treatment involving a step of forming a closed loop of tubing of the tubular set, as illustrated for example in Fig. 3 of this application, and as covered by claims 23, 32, 34 and 36. Thus, neither claim 19 nor claim 18 of U.S. Patent No. 5,772,624 should be used in a double patenting rejection against claims 23, 32, 34 and 36.

With respect to the rejection of claims 23-37 under the doctrine of double patenting over the claims of U.S. Patent No. 6,387,069, a Terminal Disclaimer is enclosed.

Accordingly, allowance of this application is respectfully requested.

Respectfully submitted,

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